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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------|
| 10/807,999 | 03/24/2004 | Mark H. Falahee | FLH-11702/29 | 4663 |
| 7590 | 04/26/2005 | | EXAMINER | |
| John G. Posa Gifford, Krass, Groh, Sprinkle, Anderson & Citkowski, P.C. 280 N. Old Woodward Ave., Suite 400 Birmingham, MI 48009-5394 | | | | ROBERT, EDUARDO C |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3732 | |
| DATE MAILED: 04/26/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/807,999 | FALAHÉE | |
| | Examiner | Art Unit | |
| | Eduardo C. Robert | 3732 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 February 2005.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1 and 3-13 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1 and 3-13 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 04 February 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 13 is objected to because of the following informalities:

Claim 13 is a duplicate of claim 12 and it should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 8, 9, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Steffee (U.S. Patent No. 4,648,388).

Steffee discloses a system comprising a bone anchor 52, e.g. screw, having a proximal and distal ends and an outer sidewall. The system also includes a connector or elbow having a portion that engages with the bone anchor 52 and an arm that engages an stabilizing rod 30 (see Figures 1-6). The proximal end of the bone anchor is positionable near or at a surface of a bone. The rod is positioned transverse to the arm (see for example Figure 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffee (U.S. Patent No. 4,648,388) in view of Hunt (U.S. Patent 324,768).

Steffee discloses the claimed invention except for the anchor including outwardly tangs or barbs. Hunt teaches to provide screws with an outwardly tang or barb in order to lock the screw after it has been screw home (see page 1, lines 12-14). It would have been obvious to one skill in the art at the time the invention was made to construct the system of Steffee with the anchor, i.e. screw, having an outwardly tang or barb in view of Hunt, in order to lock the screw in position thus preventing that it is removed. With regard to the tang or barb are tangs or barbs, it is noted that it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

Applicant's arguments filed on 2/4/05 have been fully considered but they are not persuasive.

In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of

primary and secondary references. In re Nomiya, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA) 1969. In this case, Steffee discloses the claimed invention except for the anchor, i.e. a screw, including outwardly tangs or barbs and Hunt teaches a screw with an outwardly tang or barb. Hunt further disclose that the purpose of providing a screw with tangs or bards is to lock the screw after it has been screw home (see page 1, lines 12-14). Thus, clearly Hunt provides enough suggestion and motivation for one skill in the art to provide another screw, e.g. the screw of Steffee, with tangs or barbs in view of Hunt, in order to lock the screw in position, i.e. home, and thus preventing that it is removed.

In response to Applicant's argument that Steffee and Hunt are nonanalogous art, it has been held that the determination that a reference is from a nonanalogous art is twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. In re Wood, 202 USPQ 171, 174. In this case, the references are within the field of the inventor's endeavor, e.g. screws and clamps and rods, and Steffee and Hunt are related to the field of screws and how they are designed to function to attach and be attached to other structures. Furthermore, the issue of providing tangs or barbs to a screw to assist with fixation is a problem clearly related to the Hunt reference which clearly teaches that to provide a screw with tangs or barbs is old and well known in the art for the purposes of fixing the screw in

place, as Hunt called it , to lock the screw after it has been screw home.

In response to applicant's argument that he does not understand how Steffee reads on the limitation "wherein the proximal end of the bone anchor is at or near the surface of a bone once in position", it is noted that this is just functional language, it is a step of how the anchor is intended to be used. It is noted that **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations**. Ex parte Masham, 2 USPQ2d 1647 (1987). In the current case the reference(s) show all the structural limitations.

In response to applicant's argument that Steffee does not show an elbow, it is noted that Steffee clearly shows what can be considered an elbow, e.g. part 104.

Conclusion

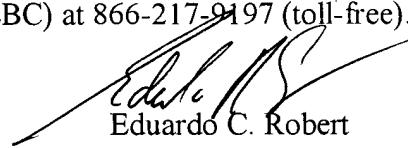
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 571-272-4719. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 571-273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.